"Let's Get it Straight"
BACKTALK

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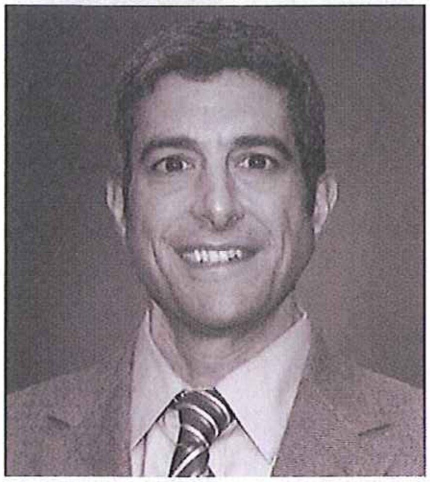
Robotic-Guided Placement Of Implants For Spine Surgery



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Introduction

Pedicle screws and rods are commonly employed to stabilize the spine while the bone fuses. Pedicle screw fixation has been validated for the surgical treatment of debilitating degenerative spine conditions, scoliosis,[1,2] spondylolis- mentation procedures are associated with pain, tissue scarring, paraspinal muscle injury, violation and damage to the proximal facet joint, and extended recovery times.[23] More recently developed, less invasive methods of screw implantation are reported to ameliorate some of these disadvantages.[24-26] There appears to be growing evidence that less invasive approaches achieve as good clinical outcomes as conventional open surgery while significantly improving efficiencies and economics, achieving lower direct institutional cost by providing reduced post-operative pain, shorter hospitalization, earlier rehabilitation and lower transfer rates to inpatient rehabilitation. However, and paradoxically, only a small portion of all spinal surgeries are conducted in this fashion and most surgeons still rely on conventional open methods - largely due to the presumed higher incidence of screw malpositioning,[27,28] higher overall procedure time, and greater exposure to ionizing radiation that are associated with the less invasive techniques.

When treating patients with a spinal deformity, the goal of surgical intervention is to prevent further progression, correct the deformity, obtain a solid biological fusion, protect the neurological elements, fuse the least number of segments, and avoid complications. When treating these patients the placement of pedicle screws raises the con- technological advances, these modalities have their own set of limitations including: accurate registration of the pre-operative images with the physical anatomy which requires the exposure of bony structures, and the need to maintain line-of-sight between the target, the field and the tracking cameras. In addition, the operating surgeon must acquire the skill of operating while looking at a computer screen rather than at the surgical field.

The emergence of robotic-guided spine surgery – facilitated by developments in robotics, miniaturization and image processing – may potentially address these shortcomings. Current robotic guidance technologies use standard pre-operative CT scans to create a surgical blueprint of the procedure in a 3D virtual environment, and couples the pre-operative plan with sophisticated software and an advanced robotic arm to facilitate tool positioning with exacting precision. Extremely accurate placement of spinal implants can be achieved even under the most challenging conditions such as severe scoliosis, revision and reoperation cases in the presence of altered or even absent anatomical landmarks, less invasive and percutaneous approaches, and even complex tumor reconstructions in poor quality (e.g. osteoporotic) bones.[34-39]

In addition to unparalleled accuracy, the detailed pre-operative planning step facili-

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patient's anatomy. Likewise, the robotic arm then facilitates the surgical plan much like the airplane's computer facilitates the pilot's flight plan.

When considering robotic guided surgery, one must appreciate that the robot is not actually performing the surgery. Both planning and surgical procedures are done by the surgeon with the robot facilitating the accurate execution of the plan. Likewise, one must recognize that the robot will not make a bad surgeon good. The robot is a tool that can make a good surgeon more precise and efficient.

Benefits of Robotic-Guided Surgery - the Clinical Evidence

The principal benefits of placing spinal implants using robotic guidance ultimately relates to patient safety, optimizing outcomes and protecting OR staff from excessive radiation.

Safety

The benefits of robotic guided implant placement has been shown by recent studies of the SpineAssist® system (Mazor Robotics, Caesarea Israel). To date it has been used in over 2,000 surgeries worldwide for the surgical placement of more than 7,000 spinal implants, with no instances of nerve or spinal cord damage as a result of surgery.

With the increased use of pedicle screw constructs in the surgical treatment of spinal disorders, improved accuracy and a lower radiation exposure are intuitively beneficial. Misplaced screws can lead to complications, including dural tear,[15,42] injury to the spinal cord or nerve roots,[15,42,43] neurologic deficit,[42,43] and skeletal perforation.[1,42] The rate of pedicle screw mal-positioning ranges from 0% to 25%, depending on the case's degree of complexity and the surgeon's level of experience.[2-9] Schizas *et al* in a recent meta-analysis looked at 130 studies resulting in 37,337 total pedicle screws implanted; they report a 13.4% in-vivo misplacement rate in the thoraco-lumbar spine when standard free-hand technique is utilized for implantation (23 studies, 10,107 screws). A study of 112 consecutive patients, comparing standard technique to robotically-guided thoracolumbar surgery, found the robotic group (55 patients) had only 1.1% misplaced screws (ref); this rate was stable regardless of whether an open or minimally-invasive approach was implemented (20 and 35 patients, respectively); fluoro usage was cut in half with the use of robotics despite the fact that the majority of robotic cases were MIS while all the standard-technique cases were open, and there was no significant difference in length of surgery.[27] Although most misplaced screws are asymptomatic,[8,10,11] the prospect of neurologic and/or bone injury or compromised stabilization,[3,12,13] especially when manipulating the thoracic spine,[14-16] justify the development of guidance tools as an aid in the appropriate and safe screw orientation during insertion.

Scoliosis, Deformities and Revisions

In a recent study of 80 patients with adolescent scoliosis[44] – 14 male, 66 female, average age 14.4 YO, who underwent open posterior spinal instrumentation and fusion, with an average curvature of 66.5 degrees (range 46-95) - the robotic system guided 1,163 screws into their precise locations with 99.9% accuracy (one screw placed lateral to pedicle, asymptomatic), zero device or implant complications and zero repeat operations required. This is in contrast to the previously cited average implant misplacement rate in scoliosis surgery of 15.8% according to a recent meta-analysis[29].

Deformities and revision surgeries are ideal indications for the utilization of robotic technology. This type of technology will provide the surgeon with a strong sense of security in challenging clinical situations when a deformity or altered landmarks make it hard to recognize normal landmarks. This advanced technology may also allow inclusion of patients with complicated anatomical deformities, who are often excluded from pedicle screw-based surgery options (see figure 1).

Less invasive surgical techniques

Muscle-sparing interventions will also benefit from the use of robotic guidance; indeed to date most procedures utilizing the robot involved or percutaneous approaches (see figure 2).

Pechlivanis *et al*[45] reported a prospective series of 29 patients receiving instrumented PLIF with percutaneous insertion of pedicle screws, combined with spinal decompression, discectomy, and implantation of PEEK cages performed through a small midline incision. 133 (L2-S1) screws were inserted percutaneously under robotic guidance. Utilizing post-op CTs and the 2mm incremental classification system by Gertzbein and Robbins,[46] they report 98.5% accurate placement; accurate placement was defined as entirely within the pedicle (91.7%) or with a breach smaller than 4mm (7.5%). Instrumentation was performed by four different surgeons, thus minimizing user-dependency of outcomes. They further report no screw-related or

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robot-related complications, and go on to emphasize that these outcomes compare very favorably to the commonly-reported deviation and complication rates.

In a separate large-scale cadaveric study, the authors recently examined the effect of the technology on screw placement accuracy, radiation exposure and length of surgery in percutaneous pedicle screw implantation.[47] 234 pedicle screws were implanted in 12 cadavers (study group: 15 surgeons, 197 screws, 10 specimens; control group: two surgeons, 37 screws, two specimens). The results were dramatic: the study group had significantly more accurate placements relative to control (average deviation 1.1mm ± 0.4 mm vs 2.6mm ± 0.7mm; $p < 0.0001$) and fewer pedicle wall breaches of ≥4 mm (average 1.5% vs 5.4%). In addition, surgeons in the study group used fluoroscopy much more sparingly (average 0.9 seconds per screw vs 33.0 seconds per screw) and as a result were exposed to much less radiation (average 4.2 vs 136 mrem); they were also able to complete the procedure more quickly. In conclusion, use of robotic guidance increased the accuracy of percutaneous pedicle screw placement by 58%, reduced the risk of neurologic injury (as measured by breaches >4 mm) by 72%, diminished surgeons' exposure to radiation by 97% and shortened procedure time by 36%.

A Technical Note - How it all Works

Robotic guided surgery involves two key components: A computerized workstation that enables surgeons to upload a patient's CT scan and plan the surgical procedure (see figure 3), and a robotic arm that facilitates the surgeon's preoperative plan (see figure 4).

At the time of surgery a reference frame is securely mounted onto the patient's bony anatomy which is followed by two fluoroscopic images in the AP and a 60-degree oblique planes. The software automatically merges ("registers") the intra-op fluoroscopy images with the pre-op CT and the pre-operative plan. The two x-rays with the reference frame serve to tell the robot where the spine is in 3-D space. The robotic software then matches the patient's anatomy with these x-rays by merging them with the CT scan and the pre-operative plan. This process is very similar to how GPS (global positioning systems) combines satellite images and digital maps to plan a route from one point to another.

Once image registration is completed and verified, the robotic arm is mounted onto the reference frame and with the press of a button the robot's arm is dispatched to the pre-planned screw insertion position with utmost accuracy, thereby allowing the introduction of implants through percutaneous or minimally invasive approaches at the exact desired location on the spine.

Robotic guided surgery has been shown to be accurate to less than half a millimeter. The robot enables surgeons to plan the optimal surgery ahead of time using a computed tomography (CT)-based 3D simulation of the patient's spine – and then execute the plan with flawless accuracy.

A Final Thought

Robotics has been revolutionizing surgery in a growing number of medical disciplines for several years – including urology, gynecology, cardiology and others. As importantly, it may change many aspects of the way we practice spinal surgery.

Bone-mounted robotic guidance can facilitate accurate placement of pedicle screws, thereby reducing the risk of errantly placed screws and their associated morbidity. Nonetheless, some users have found the system as useful for non-pedicle-screw procedures such as biopsies, vertebral augmentations (vertebroplasty and kyphoplasty) and tumor resections. The technology offers the benefits of precise pre-operative planning for the most suitable entry points, and the most appropriate trajectories and intra-operative execution plans. All of these parameters can be computed even in the presence of severe deformities and loss of anatomical landmarks.

The use of surgical robots has been proven to provide enhanced accuracy in various open, less invasive, and percutaneous spinal procedures.[34-38] Overall, the advantages associated with a robotic guidance system may make the surgeon more at ease about offering MIS or percutaneous surgical options to patients and more comfortable about implementing pedicle-based fixation in general – while at the same time increasing the surgeon's own sense of safety by dramatically reducing their exposure to fluoro radiation.

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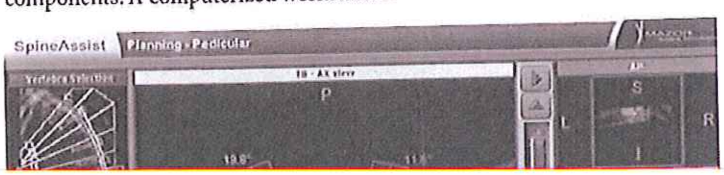

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When considering robotic guided surgery one must appreciate that the robot is not actually doing the surgery. It is still the surgeon doing the surgery with the robot facilitating the pre-operative plan. Likewise, one must recognize that the robot will not make a bad surgeon good. The robot is a tool that will make a good surgeon more precise and efficient. With the recent introduction of this cutting-edge technology into spine surgery, the promise of robotics is poised to positively affect the health and quality of life of many more patients.

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